

REMARKS

At the outset, Applicants representative wishes to thank Examiner Kerr for the telephonic interview on December 5, 2005 to discuss possible amendments to the pending claims. Claims 1 and 3 have been amended. Upon entry of these amendments, Claims 1-4, 7, 10, 12-17, and 30 will be pending and under active consideration. Claims 1 and 25 are independent.

In particular, Claim 1 has been amended to delete reference to the term diabetes. Claim 3 has been amended to clarify that the oxidation-resistant variant thereof is a α_1 -antitrypsin Met³⁵⁸ variant and that the free radical-resistant variant thereof is a α_1 -antitrypsin Met³⁵⁸ variant. Applicants submit respectfully that the recitation of Met³⁵⁸ variants finds support at page 5, lines 17-30 of the specification as filed and, thus, does not represent new matter.

In accordance with the requirements of 37 C.F.R. Section 1.121(h), Applicants have provided herewith the required entire "Amendments to the Claims". This document provides the full set of pending Claims. The document also provides the claim status identifier required for each claim. This set of claims replaces all prior versions and listing of claims in the application.

Applicants respectfully request entry remarks made herein into the file history of the present application.

The Rejection of Claims 1, 3, 4, 10, 15, and 30 Under 35 U.S.C. § 102(e) as Being Anticipated by Lezdey *et al* (U.S. Patent No. 6,124,257).

At page 7 of the Final Office Action, Claims 1, 3, 4, 10, 15, and 30 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Lezdey *et al*. ("Lezdey"). The Examiner indicates that Lezdey discloses a method of treating patients having a non-pulmonary disease, in particular, diabetes, with α_1 -antitrypsin. Applicants respectfully traverse the rejection. Applicants respectfully submit that Lezdey does not anticipate claims 1, 3, 4, 10, 15, and 30 as amended.

Without acquiescing in the propriety of the rejection, and solely to advance prosecution, Applicants have amended Claim 1 to no longer recite the term diabetes. In view of the amendment to claim 1, Applicants respectfully submit that rejection of Claims 1, 3, 4, 10, 15, and 30 under § 102(e) has been overcome and withdrawal thereof is respectfully requested.

The Rejection of Claims 3 and 4 Under 35 U.S.C. § 112, First Paragraph

At page 5, paragraph 13, of the Final Office Action, Claims 3 and 4 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. At page 5, paragraph 14, of the Final Office Action, claims 3 and 4 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was allegedly not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse the rejections.

Applicants respectfully submit that Claim 3 has been amended to clarify that the oxidation-resistant variant thereof is a α_1 -antitrypsin Met³⁵⁸ variant and that the free radical-resistant variant thereof is a α_1 -antitrypsin Met³⁵⁸ variant. Accordingly, in view of the amendment to Claim 3, Applicants respectfully submit that the rejection of Claims 3 and 4 under 35 U.S.C. §112, first paragraph, as allegedly lacking written description and enablement has been overcome.

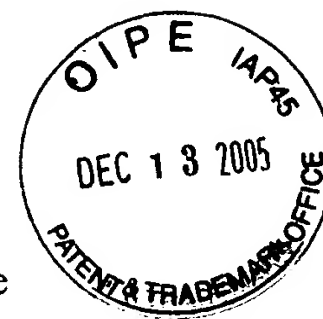
The Rejection of Claims 3 and 4 Under 35 U.S.C. § 112, Second Paragraph

At page 4, paragraph 11, of the Final Office Action, Claims 3 and 4 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. In particular, the Examiner notes that the phrase oxidation resistant or free radical Met³⁵⁸ variant is confusing. Applicants respectfully traverse the rejection.

Applicants respectfully submit that Claim 3 has been amended to clarify that the oxidation-resistant variant thereof is a α_1 -antitrypsin Met³⁵⁸ variant and that the free radical-resistant variant thereof is a α_1 -antitrypsin Met³⁵⁸ variant. Accordingly, in view of the amendment to Claim 3, Applicants respectfully submit that the rejection of Claims 3 and 4 under 35 U.S.C. §112, second paragraph, has been overcome.

The Objection of Claims 2, 7, 12-14, 16, and 17

At page 3, paragraph 8, of the Final Office Action, Claims 2, 7, 12-14, 16, and 17 are objected to as being dependent upon a rejected claim. In view of the amendments to Claims 1 and 3, Applicants respectfully submit that the objection to Claims 2, 7, 12-14, 16, and 17 has been obviated.



CONCLUSION

Applicant submits that the application is in condition for allowance. Favorable reconsideration, withdrawal of the rejections set forth in the above-noted Office Action, and an early Notice of Allowance are requested.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should be directed to our address given below.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees due in connection with this filing to Deposit Account 50-1710 or credit any overpayment to same.

Respectfully submitted,

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